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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/466,778 12/20/99 HASTINGS

9 PF487

022195 HM22/1023
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

EXAMINER

MITRA, R

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary	Application No. 09/466,778	Applicant(s) HASTINGS ET AL.	
	Examiner Rita Mitra	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 20) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Status of the Claims

Applicants' amendment and response to office action dated April 25, 2001 (paper #10) is acknowledged. Amendments to specification has been entered. Therefore, claims 23-80 are currently pending to which the following grounds for rejection are or remain applicable.

Response to Remarks and Arguments

Withdrawal of Objections

The objection to the specification is withdrawn in light of Applicants' amendments to the specification.

Maintenance of Rejections

Rejection under 35 U.S.C. 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23-80 remain rejected **under 35 U.S.C. 101** because the claimed polypeptides are not supported by either a specific and substantial asserted utility or a well established utility because the specification fails to assert any utility for the claimed protein.

The rejection has been set forth in the previous office actions. In response, applicants traverse the foregoing rejection and argue (pages 10-14) that the claimed invention is supported by a well established, credible, specific and substantial utility as the invention features a novel hyaluronan-binding protein BM-HABP (i.e., a novel hyaluronan-binding protein BM-HABP comprising amino acid sequence set forth in SEQ ID NO: 11). Further, applicants assert that on the basis of structural similarity to TSG-6 the protein BM-HABP is identified as a member of 'TSG-6 (HABP)' family. Applicants' arguments are fully considered but not found persuasive because the amendments fail to provide any biological activity of the polypeptides claimed. Applicants indicate at page 12 that Tao et al. (Reference AD) also teach that their protein of Q9NRY3 contains a hyaluronan-binding domain, therefore since BM-HABP is structurally similar to Tao et al.s' protein Applicants assert that BM-HABP of the present invention would have the similar function and utility as in Tao et. al.s' protein. The argument is not persuasive because Applicants have not provided any activity of the BM-HABP protein which can be correlated with the activity of Tao et al.s' protein. The prior art (Reference AD) does not provide a support in establishing utility of the claimed invention. Therefore, the claimed invention is not supported by a well established, credible, specific and substantial asserted utility.

Rejection under 35 U.S.C. 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-80 remain rejected under **35 U.S.C. 112, first paragraph**. Specifically, since the claimed polypeptides are not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Rejection under 35 U.S.C. 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention..

Claims 31, 32, 36, 37, 41-44, 48-51, 55-68 and 72-77 remain rejected under **35 U.S.C. 112, second paragraph**. Specifically, since the amendments do not provide any information to support the functional properties of the claimed polypeptide fragments. Applicants remark on page 15 that the specification teaches the use of the polypeptide fragments as immunogens to raise antibodies, which does not require biological activity. Applicants' arguments are not persuasive because without knowing the activity of the antibodies raised from the polypeptide fragments how one can practice the invention without knowing the function of those antibodies, which would be, raised against the claimed polypeptide fragments. Therefore 112, second paragraph rejection remains.

Conclusion

Claims 23-80 are rejected.

This is a Continued Prosecution Application of applicant's earlier Application No. 09/122383 under 37 CFR 1.53(d). All claims are drawn to the same invention claimed in the earlier application and were finally rejected on the grounds and art of record in the Office Action mailed on May 9, 2001. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must

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conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.

October 21, 2001



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600